

08/879,139



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/879,139	06/19/97	MERRIL	C P8026-7004

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EXAMINER

WORTMAN, D

ART UNIT

PAPER NUMBER

1643

4

DATE MAILED: 02/11/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 6/19/97, 12/12/97

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

Claim(s) 31 - 40 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 31 - 40 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

*Ex. Notice to Comply... pg.*

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 1643

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1643.

Applicant is requested to update the status of parent application(s) to which reference is made in the first sentence of the specification.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given the same time period within which to comply with the sequence rules, 37 CFR 1.821 - 1.825, as is available to respond to this Office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Claims 13-30 were cancelled by preliminary amendment in Paper No. 2. Claims 1-12 were cancelled and new claims 31-40 were added in Paper No. 3. Claims 31-40 are pending and under examination at this time.

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Claims 31-40 are objected to because of the following informalities:

Claims 31, 32, 35, 36, and 40 are objected to because each ungrammatically recites "a bacteria" or "bacteria is." Since the word "bacteria" is plural, it is suggested that the claims be amended to recite, for example, either "bacteria" or "bacteria are," as appropriate.

Appropriate correction is required.

Claim 31-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an infectious disease caused by bacteria in non-human animals, does not reasonably provide enablement for treating an infectious disease caused by bacteria in a human patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification provides guidance for selecting bacteriophage that have a longer half-life by passaging through an animal and then using these bacteriophages to treat an infectious disease caused by bacteria in animals of the same species as the animal in which the bacteriophage selection was done. There is no guidance particularly directed to selecting bacteriophage by passaging through humans, nor is there guidance for selecting bacteriophage by passaging through an animal or animals and then using the animal-selected bacteriophage to treat humans. There is no indication that a particular animal model is suitable for obtaining results that could reasonably be extrapolated to treating disease in a human patient. One of skill in

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the art would require more than mere assertion that such procedures might be performed in order to successfully treat infectious disease in humans, given the state of the art at the time the invention was made with respect to using bacteriophage to treat human disease, the lack of knowledge of how the human immune system reacts to the presence of bacteriophage, and the unpredictability inherent in the art of treating diseases in humans.

Claims 31-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is indefinite because it recites "bacteriophage" in lines 4 and 5 and "phage" in line 6. Consistent terminology should be used throughout the claims for improved clarity.

Claim 34 is indefinite because it recites the abbreviation "HDS" without explanation. For clarity, an abbreviation should be spelled out in full the first time it appears in the claims. Claim 34 is also indefinite because it recites material within parentheses ("(serial passage)"). If this material is necessary in order to understand the claim, it should be incorporated into the claim without the use of parentheses. If it is unnecessary and indeed parenthetical in nature, it should be deleted as superfluous.

Claims 34 and 39 are indefinite because each depends from a cancelled claim.

Claim 37 is indefinite because it depends from claim 31 and recites "administered ... to an animal's lungs." Such limitation is not

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understood in view of the fact that claim 31 is drawn to a method of treating a human patient.

Claim 40 is indefinite because it is not clear whether "in a dosage effective to substantially eliminate the bacteria" is intended to refer to "an antibiotic and/or a chemotherapeutic agent," or to "a bacteriophage specific for said bacteria," or to both. Clarification is needed.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-33 and 35-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31, 32, and 34-40 of copending Application No. 08/811,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to overlapping subject matter insofar as both sets of claims encompass treatment of human patients using bacteriophage with a longer half-life in the patient's circulatory system than the corresponding

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wild-type phage. With respect to claim 40 of the instant application, it would additionally have been obvious to use antibiotics in addition to the bacteriophage for treating infectious disease as in claims 31, 32, and 34-40 of copending Application No. 08/811,344, because of the well-known anti-bacterial properties of antibiotics.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 40 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3-11 of U.S. Patent No. 5,688,501 to Merril et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to use antibiotics in addition to the bacteriophage for treating infectious disease as in claims of US Patent No. 5,688,501 because of the well-known anti-bacterial properties of antibiotics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knodel, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Donna C. Wortman, Ph.D.

February 10, 1998